REMARKS

Applicant has carefully reviewed the Office Action mailed March 6, 2007 and offers the following remarks to accompany the above amendments.

Claims 1, 11, 13, and 17-38 are pending in the present application. Claims 2-10, 12, and 14-16 were previously cancelled. Claims 39 and 40 are added. Accordingly, claims 1, 11, 13, and 17-40 are pending.

Applicant would like to thank the Examiner for indicating that claims 36-38 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, as well as to correct for antecedent basis indicated in the Office Action mailed March 6, 2007. Applicant reserves the right to rewrite claims 36-38 in independent form at a later date.

Claim 36 was objected to due to the phrase "and, in being adapted to control the reciprocating regulator to..." presenting an improper antecedent basis. Applicant has amended claim 36 to correct the antecedent basis issue.

Claims 1, 11, 13, 17, and 21-35 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,997,482 to Vaschillo et al. (hereinafter "Vaschillo") in view of U.S. Patent Application No. 2002/0185126 A1 to Krebs (hereinafter "Krebs"). Applicant respectfully traverses. For the Patent Office to combine references in an obviousness rejection, the Patent Office must establish *prima facie* obviousness by showing where each and every element is taught or suggested in the combined references. MPEP § 2143.03.

Prior to addressing the merits of the rejections, Applicant offers the following summary of the present invention as claimed. The present invention provides for monitoring a heartbeat rate of a care recipient to determine a heart rate variability cycle of the care recipient, wherein the heart rate variability cycle includes periods of increasing and decreasing heartbeat rate. An indicator is provided to the care recipient indicative of the periods of increasing and decreasing heartbeat rate. The care recipient is instructed to synchronize inhalation and exhalation phases of a breathing cycle with the periods of increasing and decreasing heartbeat rate, respectively, and a therapeutic gas is dispensed to the care recipient during the inhalation phase of the breathing cycle based upon the heart rate variability cycle.

In contrast, the system of the Vaschillo reference monitors the heart rate variability cycle and the respiratory cycles of a person and performs a spectral analysis (e.g., Fourier analysis) of

the two cycles. The Vaschillo reference provides a single reference signal indicative of the phase shift between the two cycles. The person is instructed to breathe according to the single phase shift reference signal. The system of the Vaschillo reference does not dispense a therapeutic gas to the person during the inhalation phase of the breathing cycle and does not dispense therapeutic gas based upon heart rate variability.

The system of the Krebs reference teaches an artificial respiration gas-supply system for adaptively dosing a gas to individual patients suffering from chronic breathing difficulties, such as asthma and chronic obstructive pulmonary disease (COPD). The system of the Krebs reference controls gas metering to minimize patient side effects from the administered gas. The patient's heart rate and oxygen saturation in the peripheral blood may be measured by use of pulse-oxymeters to protect the patient from an excessive application of gas. There is no teaching within the Krebs reference of applying therapeutic gas based upon heart rate variability. Additionally, there is no teaching within the Krebs reference of coordinating breathing, and thus the application of therapeutic gas, with the heart rate variability cycle for purposes of respiratory therapy.

Claim 1 recites, among other things, "monitoring a heartbeat rate of the care recipient to determine a heart rate variability cycle . . . instructing the care recipient to synchronize inhalation and exhalation phases of a breathing cycle . . ." with the heart rate variability cycle. Claim 1 also recites "dispensing a therapeutic gas to the care recipient during the inhalation phase of the breathing cycle," where the inhalation phase of the breathing cycle has been synchronized with the "periods of increasing" heartbeat rate of the heart rate variability cycle.

The Patent Office asserts that the Vaschillo reference discloses the claimed invention except for dispensing a therapeutic gas to the care recipient during the inhalation phase of the breathing cycle, and asserts that the Krebs reference cures this admitted deficiency of the Vaschillo reference. (See Office Action mailed March 6, 2007, page 3). However, this statement is incorrect. Applicant respectfully submits that neither the Vaschillo reference nor the Krebs reference, either alone or in combination, teach or suggest dispensing a therapeutic gas to a care recipient during an inhalation phase of a breathing cycle which has been synchronized with periods of increasing heartbeat rate of the care recipient's heart rate variability cycle. Accordingly, the Patent Office has not established *prima facie* obviousness because it has not

shown where each and every element is taught or suggested in the combined references. Accordingly, the rejection of claim 1 should be withdrawn for at least this reason.

The Patent Office also asserts that the Krebs reference and the Vaschillo reference both disclose methods of monitoring heart rate and inhalation and exhalation phases of a patient in order to treat a respiratory condition and that it would be obvious to modify the teachings of the two references to arrive at the claimed subject matter. (See Office Action mailed March 6, 2007, page 4). However, Applicant respectfully submits that the Krebs reference monitors the breathing cycle alone to determine when to administer gas to the patient and only monitors heart rate to determine whether an over-application of gas has retrospectively occurred to prevent side effects.

Additionally, monitoring heart rate is distinct from determining heart rate variability, as claimed. Heart rate is simply the number of beats per minute. In contrast, heart rate variability is a measurement of the variation of the heart rate over time. Furthermore, as discussed above, the Krebs reference monitors heart rate only to determine whether the application of gas to the patient is excessive and to prevent side effects and provides no teaching of how to determine whether the application of gas is excessive based upon heart rate. As such, there is no teaching or suggestion within either the Vaschillo reference or the Krebs reference, either alone or in combination, of dispensing a therapeutic gas to a care recipient during an inhalation phase of a breathing cycle which has been synchronized with periods of increasing heartbeat rate of the care recipient's heart rate variability cycle. Accordingly, the rejection of claim 1 should be withdrawn for at least these additional reasons. Claims 11, 13, 17, and 21-24 depend, either directly or indirectly, from claim 1 and the rejection of claims 11, 13, 17, and 21-24 should be withdrawn for at least the same reasons as claim 1. Applicant reserves the right to provide additional arguments against the rejection of claims 11, 13, 17, and 21-24 in the future.

Claim 25 includes elements similar to claim 1, including, among other things, dispensing a therapeutic gas to a care recipient during an inhalation phase of a breathing cycle which has been synchronized with periods of increasing heartbeat rate of the care recipient's heart rate variability cycle. As discussed above, this element is not taught or suggested by the combination of the Vaschillo reference with the Krebs reference. Accordingly, the rejection of claim 25 should be withdrawn for at least the same reasons as claim 1. Claims 26-35 depend, either directly or indirectly, from claim 25 and the rejection of claims 26-35 should be withdrawn for at

least the same reasons as claim 25. Applicant reserves the right to provide additional arguments against the rejection of claims 26-35 in the future.

Applicant reserves the right to provide additional arguments against the Vaschillo reference and the Krebs reference in the future, if needed. Applicant respectfully submits that claims 1, 11, 13, 17, and 21-35 are in condition for allowance and notice of the same is requested at the earliest possible date.

Claims 18-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Vaschillo in view of Krebs and in further view of U.S. Patent No. 6,435,182 B1 to Lutchen et al. (hereinafter "Lutchen"). Applicant respectfully traverses. The standards for obviousness are set forth above.

Claims 18-20 depend indirectly from claim 1. As such, the rejection of claims 18-20 should be withdrawn for at least the same reasons as claim 1. Applicant reserves the right to provide additional arguments against the rejection of claims 18-20 in the future, if needed. Applicant respectfully submits that claims 18-20 are in condition for allowance and notice of the same is requested at the earliest possible date.

Claims 39 and 40 have been added. No new subject matter is added by these amendments. Claims 39 and 40 include subject matter previously claimed in claims 1, 17, 25, and 28, respectively. Furthermore, support for claims 39 and 40 can be found within the present Application. (See Specification, page 6, lines 6-9 and page 7, lines 30-32). Applicant respectfully submits that, as discussed above, the cited references do not teach or suggest synchronizing a regulator with the care recipient's heart rate variability cycle to dispense a therapeutic gas to a care recipient during periods of increasing heartbeat rate. As such, claims 39 and 40 are allowable and notice of the same is requested at the earliest possible date.

The present application is now in condition for allowance and such action is respectfully requested. The Examiner is encouraged to contact Applicant's representative regarding any remaining issues in an effort to expedite allowance and issuance of the present application.

Respectfully submitted,

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Date: May 17, 2007
Attorney Docket: 1119-005